Serial No.: 10/646,545 Confirmation No.: 9714 Filed: August 21, 2003

For: MEDICAL LEAD CONNECTOR SYSTEMS WITH ADAPTERS (as amended)

Remarks

The Office Action of August 18, 2009 has been received and reviewed. In this response, claims 1, 11, 13, and 16-22 have been amended and no claims have been canceled or added. Therefore, claims 1-6, 11-13, and 16-22 are pending. Reconsideration and withdrawal of the rejections are respectfully requested as discussed herein.

Interview Summary

Applicants' representative, Matthew C. Goeden (Reg. No. 63,560), discussed the 35 U.S.C. §102 rejection with the Examiner, Alyssa M. Alter, on December 15, 2009. Applicants' representative discussed with the Examiner her interpretation of the prior art in view of the rejected claims and the differences between the prior art (i.e., Pohndorf et al.) and the claims. Further, the Examiner noted that limitations regarding "structural differences" between the first and the second adapters may be beneficial to differentiate the claims from the prior art.

Claim Amendments

Independent claims 1, 11, 13, and 16 were amended to recite that each adapter includes electrically isolative material along the internal surface as well as further recitations to make explicit what was already implied (e.g., such further recitations are not narrowing). Support for these amendments may be found in the application as filed at, e.g., paragraphs [16]-[17] & [22].

Further, independent claim 1 was amended to recite "a set of adapters" and the preambles of independent claims 13 and 16 were amended to change "system" to "kit."

Dependent claims 17-22 were amended to remain consistent with amended independent claim 16 (from which claims 17-22 depend).

Entry and consideration of these amendments are respectfully requested.

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Claim Objections

Claims 1-6, 13, and 16-22 were objected to because of informalities. It was asserted in the Office Action that clarity is required in indicating how both adapters can be connected at the same time to the same bore. Further, it was suggested that the claims should be in "KIT" format.

Although Applicants respectfully traverse this objection, independent claims 1, 11, 13, and 16 were amended, in part, to overcome this objection. More specifically, independent claim 1 was amended to recite "a set of adapters" and the preambles of independent claims 13 and 16 were amended to change "system" to "kit." Applicants, however, reserve the right to pursue the claims as they existed prior to the amendments filed herein.

Reconsideration and withdrawal of this objection are respectfully requested.

35 U.S.C. §102 and §103 Rejections

Claims 1-5, 6, 11-13, and 16-22

Claims 1, 3-4, 6, 11-13, and 16-22 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative under 35 U.S.C. §103(a) as obvious over Pohndorf et al. (U.S. Patent No. 4,628,934).

Claim 2 was rejected under 35 U.S.C. §103(a) as being obvious over Pohndorf et al. (U.S. Patent No. 4,628,934).

These rejections are respectfully traversed.

Pohndorf et al.

Pohndorf et al. describes a hermetically-sealed pacer. The pacer includes a pacer neck having two identical lead sockets to receive two <u>identical</u> adapters. Each of the adapters is configured to receive multi-electrode pacer leads. Further, each adapter includes an electronic electrode switching/selection circuit to select which of the internal connector rings and/or pin socket are connected to the one or more of the external connector rings and/or pin socket. *See*

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Pohndorf et al., column 1, lines 9-11; column 5, lines 22-27; column 9, lines 19-23 & 32-46; and Figures 4-7.

Pohndorf et al. fails to teach each element of claims 1-4, 6, 11-13, and 16-22

Independent claims 1, 11, and 13 recite, among other things, a first adapter and a second adapter. Each of the first and second adapters includes one or more conductive portions, one or more electrical contact elements, and electrically isolative material. Further, at least a portion of the electrically isolative material of the first adapter is located in the same location along an internal surface thereof as at least one of the one or more electrical contact elements of the second adapter, and at least a portion of the electrically isolative material of the second adapter is located in the same location along an internal surface thereof as at least one of the one or more electrical contact elements of the first adapter.

Independent claim 16 recites, among other things, a first adapter and a second adapter. Each of the adapters includes an external contact element, an internal contact element, and electrically isolative material. Further, at least a portion of the electrically isolative material of the first adapter is located at the same location along an internal surface thereof as the internal contact element of the second adapter, and at least a portion of the electrically isolative material of the second adapter is located at the same location along an internal surface thereof as the internal contact element of the first adapter.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See M.P.E.P. § 2131.

To establish a *prima facie* case of obviousness, there must be a finding that the prior art included each element claimed, although not in a single prior art reference. *See* M.P.E.P. § 2143.

Pohndorf et al. does not teach each element of claims 1-4, 6, 11-13, and 16-22 as required for anticipation and *prima facie* obviousness. For example, nothing has been identified by the Office Action within the disclosure of Pohndorf et al. that teaches a first and a second adapter where at least a portion of the electrically isolative material of the first adapter is located in the

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same location along the internal surface thereof as at least one of the one or more electrical contact elements of the second adapter as recited in independent claims 1, 11, and 13, or where at least a portion of the electrically isolative material of the first adapter is located at the same location along the internal surface thereof as the internal contact element of the second adapter as recited in independent claim 16. Instead, each identical adapter 316 of Pohndorf et al. includes connector rings located at the same locations along socket 321 without any electrically isolative material located at the same location along the internal surface of the socket 321 as at least one connector ring of the other adapter. In other words, the internal structure of the identical adapters of Pohndorf et al. is identical while the internal structure of the claimed adapters is different (e.g., at least a portion of the electrically isolative material of the first adapter is located in the same location along the internal surface thereof as at least one of the one or more electrical contact elements/internal contact element of the second adapter as recited in one or more pending claims).

Further, if the adapters of Pohndorf et al. were modified such that an adapter included electrically isolative material at the same location along the internal surface of the socket 321 as at least one connector ring of the other adapter, then such modification would render the modified adapter of Pohndorf et al. unsatisfactory for its intended purpose.

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See* M.P.E.P. §2143.01(V).

An intended purpose of the adapters of Pohndorf et al. is that one may be able to use the electronic electrode switching/selection circuit to select one or more of the internal connector rings or pin socket (that are electrically coupled to the proximal end of a multi-electrode lead 312, 314) to be connected to one or more of the external connector rings or pin socket (that are electrically coupled to a pacer unit with one or more feed-throughs). In other words, the adapters of Pohndorf et al. allow a user to select one or more of the electrodes of the multi-electrode lead to be connected to one or more of the feed-throughs of the pacer unit. If the adapters of Pohndorf

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et al. were modified such that an adapter included electrically isolative material at the same location along the internal surface of the socket 321 as at least one connector ring of the other adapter, then the modified adapter would not be able to electrically couple one of the electrodes of the multi-electrode lead to the pacer unit thereby rendering the modified adapter unsatisfactory for its intended purpose.

For at least these reasons, Applicants submit that Pohndorf et al. fails to teach each claim element of independent claims 1, 11, 13, and 16 as required for anticipation and *prima facie* obviousness.

Furthermore, because claims 2-4, 6, 12, and 17-22 are directly or ultimately dependent on independent claims 1, 11, 13, or 16, claims 2-4, 6, 12, and 17-22 are also novel and nonobvious over Pohndorf et al. for the same reasons as presented above for independent claims 1, 11, 13, and 16. Moreover, such claims contain recitations that further support patentability.

For example, nothing has been identified within the disclosure of Pohndorf et al. that teaches a lead connector including a plurality of sealing rings positioned distal to the plurality of connector elements, a first sealing ring of the plurality of sealing rings positioned proximal to the connector ring and a second sealing ring of the plurality of sealing rings positioned distal to the connector ring as recited in claim 4.

Reconsideration and withdrawal of these rejections are respectfully requested.

Claim 5

Claim 5 was rejected under 35 U.S.C. §103(a) as being obvious over Pohndorf et al. (U.S. Patent No. 4,628,934) in view of Peers-Trevarton (U.S. Patent No. 4,469,104). This rejection is traversed.

It has been admitted in the Office Action that Pohndorf et al. fails to disclose protrusions for each contact element and Peers-Trevarton has been provided to remedy this deficiency. *See Office Action*, August 18, 2009, page 6.

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Peers-Trevarton, however, fails to remedy the deficiencies already presented above with respect to independent claim 1, from which dependent claim 5 is directly dependent. Therefore, because claim 5 is directly dependent on independent claim 1, claim 5 is at least, for example, nonobvious over Pohndorf et al. in view of Peers-Trevarton for the same reasons as presented above for independent claim 1.

Reconsideration and withdrawal of this rejection are respectfully requested.

Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

Mueting, Raasch & Gebhardt, P.A.

P.O. Box 581336

Minneapolis, MN 55458-1336

Phone: (612) 305-1220 Facsimile: (612) 305-1228

Customer Number 26813

Date

Mark J. Gebhardt

Reg. No. 35,518

Direct Dial (612) 305-1216

CERTIFICATE UNDER 37 C.F.R. § 1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4) to the Patent and Trademark Office addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18th day of December, 2009.

Name: Deb Schurmann